510(k) Summary

K111147

JUL 19 2011

Summary Preparation Date

July 1, 2011

Submitter / 510(k) Sponsor

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Contact Person

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Regulatory Affairs Specialist
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Device Name / Classification

Device Name: Vessel Cannula
Proprietary Name: Medline Vessel Cannula
Common Name: Vessel Cannulae
Classification Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass under 21 CFR 870.4210

Predicate Device

DLP Vessel Cannulae (Medtronic), K810820

Device Description

Medline's Vessel Cannula are to be supplied as sterile, non-pyrogenic, single use, disposable devices. They are visually transparent and consist of a flexible, kink resistant body with a one way valve. This vessel cannula is 2 inches in length and terminates with a female luer and a soft blunt tip.

Indications for Use

Medline Vessel Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery or in vascular surgery to perfuse a vein graft or to help check for leaks in a harvested vein which will be used for a graft.

Summary of Technological Characteristics

Information included in this submission demonstrates that there are no significant differences in technological characteristics between Medline's Vessel Cannula and the cited predicate device.

Summary of Non-Clinical Testing

Biocompatibility testing of the Medline Vessel Cannula demonstrated that it meets the requirements of guidelines presented in the ISO 10993 Testing Standard. Below is a listing of the specific testing performed.

1. Sensitization
2. Irritation
3. Cytotoxicity
4. Intramuscular Implant
5. Acute Systemic Toxicity
6. Subchronic Systemic Toxicity
7. Pyrogen
8. Hemolysis (direct contact method)
9. Hemolysis (extract method)
10. Complement Activation

Functional performance testing of the Medline Vessel Cannula demonstrated device effectiveness in accordance with relevant ISO/ASTM test methods. Below is a listing of the specific testing performed.

1. Appearance
2. Dimensions
3. Direction of Flow
4. Tensile Strength
5. Leakage

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Vessel Cannula is safe, effective and substantially equivalent as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medline Industries, Inc.
c/o Mr. Matt Clausen
Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

JUL 19 2011

Re: K111147
Medline Vessel Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheters, cannula, or tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: April 21, 2011
Received: April 25, 2011

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111147

Device Name:

Medline Vessel Cannula

Indications For Use:

Medline Vessel Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery or in vascular surgery to perfuse a vein graft or to help check for leaks in a harvested vein which will be used for a graft.

Prescription Use__X_____ OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111147